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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,129	11/18/2003	Yuxin Hu	2577-161	5754

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,129	HU ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *27-41 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/7/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence search results (2)*.

DETAILED ACTION

1. Claims 1-65 are pending.

2. Applicant's election with traverse of Group I, claims 1-26, 42-61, and 63-65, including SEQ ID NO:1 encoding SEQ ID NO:2 in the reply filed on 1/3/2006 is acknowledged. The traversal is on the ground(s) that that MPEP §803.04 states that up to ten sequences constitute a reasonable number for examination purposes .

This is not found persuasive because in regards to the permissible number of sequences as specified in the MPEP, those guidelines were for EST sequences which are much shorter than the nucleic acid sequences presented in the present application, and because of the vast number of sequences now present in the current databases that must be searched, the office does not have the resources to search more than one corresponding pair of nucleic acid and amino acid sequences per application. And lastly, according to the MPEP, up to ten sequences will be examined, and one sequence is considered up to ten, for the reasons stated above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 27-41 and 62 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 1-26, 42-61, and 63-65, including SEQ ID NO:1 encoding SEQ ID NO:2 are examined in the present office action.

Specification

4. The Specification is objected to because the drawings are not referred to properly. If the drawings show Figures 1A -1H, then the Brief Description of the Drawings should recite "Figures 1A-1H", instead of "Figure 1". Correction is requested.

Claim Objection

5. Claims 1, 42, 45, 49, 63, and 64 are objected to for being drawn to non-elected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 19, 22, 24, and 58-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite for reciting "in the in a". It is not clear what is Applicants' intent.

Claims 22 and 24 are indefinite for reciting "wherein the increase in seed number is about 20%". The claim lacks a comparative basis.

Claims 58 and 59 are indefinite in the recitation "ANT" or "AXR1". The sole designation of an amino acid sequence by "ANT" or "AXR1" is arbitrary and creates ambiguity in the claims. For example, the amino acid sequence of "ANT" or "AXR1" could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to

designate a different amino acid sequence. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F .2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 60-61 and 63-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleotide sequence having greater than 50% homology to a full-length nucleotide sequence set forth in SEQ ID NO:1, wherein said homologous nucleotide sequence encodes a polypeptide which retains biological activity of the full length sequence or a method of enhancing organ development in a plant, a transformed plant cell or a transgenic plant comprising transforming a plant cell with a nucleotide sequence having greater than 50% homology to a full-length nucleotide sequence set forth in SEQ ID NO:1, wherein said homologous nucleotide sequence encodes a polypeptide which retains biological activity of the full length sequence or a nucleotide sequence having greater than 50% homology to a nucleotide

sequence that encodes the amino acid sequence of SEQ ID NO:2 wherein the encoded polypeptide retains the biological activity of the full length sequence.

Applicants disclose a cDNA microarray analysis was performed to identify genes responsive to NAA treatment in roots of 7 day-old seedlings (page 17, paragraph 61). One gene, which is identical to the putative gene At3g59900 in the Arabidopsis database, was found to be highly induced by NAA treatment and was designated ARGOS (for Auxin-Regulated Gene involved in Organ Size). Applicants disclose the cloned ARGOS cDNA is 732 bp in length and is designated SEQ ID NO:1 which encodes the putative ARGOS protein of SEQ ID NO:2 (page 17, paragraph 62). Applicants disclose "Blast search in GenBank showed that except for a putative homolog found in the rice genome, no other homolog has been identified, indicating that ARGOS is a novel protein and possibly plant specific" (page 17, paragraph 62).

The Applicants do not identify essential regions of the ARGOS protein encoded by SEQ ID NO:1, nor do Applicants describe any polynucleotide sequences that have 50% homology to SEQ ID NO:1 that encodes a functional ARGOS protein.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined

by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a ARGOS protein falling within the scope of the claimed genus of polynucleotides which have greater than 50% homology to SEQ ID NO:1 encodes a protein with the same activity as the protein encoded by SEQ ID NO:1 or wherein the polynucleotide encodes SEQ ID NO:2. Applicants only describe a single cDNA sequence of SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the ARGOS protein, it remains unclear what features identify an Arabidopsis ARGOS protein. Since the genus of ARGOS proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

8. Claims 60-61 and 63-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleotide sequence of SEQ ID NO:1 encoding SEQ ID NO:2, wherein the nucleotide sequence is operably linked to a promoter and method for enhancing organ development in a plant, a transformed plant cell, or a transgenic plant comprising said nucleotide sequence operably linked to a promoter, does not reasonably provide

enablement for a nucleotide sequence having less than 100% homology to SEQ ID NO:1, or a method of enhancing organ development in a plant, a transformed plant cell, plant or plant seed comprising a nucleotide sequence having less than 100% homology to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a nucleotide sequence having greater than 50% homology to a full-length nucleotide sequence set forth in SEQ ID NO:1, wherein said homologous nucleotide sequence encodes a polypeptide which retains biological activity of the full length sequence or a method of enhancing organ development in a plant, a transformed plant cell or a transgenic plant comprising transforming a plant cell with a nucleotide sequence having greater than 50% homology to a full-length nucleotide sequence set forth in SEQ ID NO:1, wherein said homologous nucleotide sequence encodes a polypeptide which retains biological activity of the full length sequence or a nucleotide sequence having greater than 50% homology to a nucleotide

sequence that encodes the amino acid sequence of SEQ ID NO:2 wherein the encoded polypeptide retains the biological activity of the full length sequence.

Applicants disclose a cDNA microarray analysis was performed to identify genes responsive to NAA treatment in roots of 7 day-old seedlings (page 17, paragraph 61). One gene, which is identical to the putative gene At3g59900 in the Arabidopsis database, was found to be highly induced by NAA treatment and was designated ARGOS (for Auxin-Regulated Gene involved in Organ Size). Applicants disclose the cloned ARGOS cDNA is 732 bp in length and is designated SEQ ID NO:1 which encodes the putative ARGOS protein of SEQ ID NO:2 (page 17, paragraph 62). Applicants disclose a cDNA fragment containing the ARGOS ORF was operably linked to the 35S promoter in sense orientation, and transformed into Arabidopsis plants (page 15, paragraph 54; page 16, paragraph 55). Applicants disclose transformed Arabidopsis plants exhibited enlarged leaf size, wherein the leaves exhibited a 50% to 120% increase in leaf size (page 18, paragraph 65). Applicants disclose the blade width, length and petiole length of the fifth leaf was greatly increased. Similar changes were also observed in floral organs, inflorescense stems and siliques (*Ibid*). Applicants disclose hypocotyl length was increased in de-etiolated seedlings and flowering was delayed by about one week and said plants produced 20% more seeds in each silique (page 19, paragraph 67). Applicants disclose the leaf blade of the 35S-ARGOS plants contained about 30% more cells than control plants, which suggests that cell number contributes to the enlarged organ size in ARGOS transgenic plants (page 20, paragraph 69). Applicants disclose ectopic expression of ARGOS extends the period of growth (page 20, paragraph 70) and extends the period of cell proliferation in organs (page 21,

paragraph 71). Applicants disclose ARGOS functions upstream of ANT (page 22, paragraph 74) and downstream of AXR1 (page 23, paragraph 76).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that are 50% sequence identical to SEQ ID NO:1 will encode a protein with the same activity as a protein encoded by SEQ ID NO:1. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

In fact, Applicants disclose "Blast search in GenBank showed that except for a putative homolog found in the rice genome, no other homolog has been identified, indicating that ARGOS is a novel protein and possibly plant specific. The Arabidopsis genome contains another putative gene that displays about 50% identity to ARGOS, but its organ-specific expression pattern and response to auxin are different from those of ARGOS" (page 17, paragraph 62).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the

respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 as probes or by designing primers to undisclosed regions of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant with the phenotype as disclosed above.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 60 is rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (Sept. 1999, NCBI Accession Number AI998680).

The claim is drawn to a nucleotide sequence having greater than 50% homology to a full length sequence of SEQ ID NO:1, wherein said homologous nucleotide sequence encodes a polypeptide which retains biological activity of the full length sequence.

Chen et al disclose a nucleic acid sequence exhibiting 72% sequence identity to Applicants' SEQ ID NO:1 (sequence search result attached), wherein said encoded protein retains biological activity of the full length sequence because the encoded protein exhibits 97%

sequence identity to Applicants' SEQ ID NO:2 (sequence search result attached), and as such, Chen et al anticipate the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 48 and 65 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 48 and 65 are drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent plant would overcome the rejection.

11. Claims 1-26, 42-59 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1 encoding SEQ ID NO:2;

a vector, method of enhancing organ development in a plant, method of regulating organ development in a plant, transformed plant cell or plant comprising said isolated polynucleotide.

12. Claims 2-18, 20-21, 23, 25-26, 43-44, 46-47 and 50-57 are allowable.

Claims 1, 42, 45, and 49 are objected to.

Claims 58-61 and 63-65 are not allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
February 16, 2006